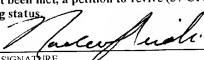


09937937.100201
533 Rec'd PCT/PTO 02 OCT 2001

FORM PTO-1300 (04-V 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER VAC.482
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (if known, see 37 CFR 1.5 09/937937)
INTERNATIONAL APPLICATION NO. PCT/US00/08759	INTERNATIONAL FILING DATE 31 March 2000	PRIORITY DATE CLAIMED 02 April 1999	
TITLE OF INVENTION VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION			
APPLICANT(S) FOR DO/EO/US HANNIGAN, Raymond, et al			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input checked="" type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A FIRST preliminary amendment.</p> <p>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information:</p> <p>Itemized postcard to be returned upon receipt: Certificate of mailing by "Express Mail" (37 CFR §1.10): I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, Express Mail Label No. EL63940013301US, on the date indicated below, and is addressed to Assistant Commissioner for Patents, Washington DC, 20231. Date: <u>10/02/01</u> By: <u>[Signature]</u> Nineteen (19) (Personal Mailing)</p>			

U.S. PATENT AND TRADEMARK OFFICE 09/937937	INTERNATIONAL APPLICATION NO PCT/US00/08759	ATTORNEY'S DOCKET NUMBER VAC.482																								
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =		CALCULATIONS - PTO USE ONLY <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 100.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 100.00		\$																					
\$ 100.00																										
\$																										
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$		\$																					
\$																										
\$																										
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">CLAIMS</th> <th style="width: 20%;">NUMBER FILED</th> <th style="width: 20%;">NUMBER EXTRA</th> <th style="width: 20%;">RATE</th> <th style="width: 20%;">\$</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>10 - 20 =</td> <td>0</td> <td>x \$18.00</td> <td>\$ 0.00</td> </tr> <tr> <td>Independent claims</td> <td>1 - 3 =</td> <td>0</td> <td>x \$80.00</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="3"></td> <td>+ \$270.00</td> <td>\$ 0.00</td> </tr> </tbody> </table>		CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	Total claims	10 - 20 =	0	x \$18.00	\$ 0.00	Independent claims	1 - 3 =	0	x \$80.00	\$ 0.00				+ \$270.00	\$ 0.00	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 100.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 100.00		\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$																						
Total claims	10 - 20 =	0	x \$18.00	\$ 0.00																						
Independent claims	1 - 3 =	0	x \$80.00	\$ 0.00																						
			+ \$270.00	\$ 0.00																						
\$ 100.00																										
\$																										
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 100.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 100.00		\$																					
\$ 100.00																										
\$																										
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$		\$																					
\$																										
\$																										
SUBTOTAL =		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 100.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 100.00		\$																					
\$ 100.00																										
\$																										
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 0.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 0.00		\$																					
\$ 0.00																										
\$																										
TOTAL NATIONAL FEE =		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 200.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 200.00		\$																					
\$ 200.00																										
\$																										
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 0.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 0.00		\$																					
\$ 0.00																										
\$																										
TOTAL FEES ENCLOSED =		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">\$ 200.00</td> <td style="width: 40%;"></td> </tr> <tr> <td>\$</td> <td></td> </tr> </table>	\$ 200.00		\$																					
\$ 200.00																										
\$																										
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>50-0326</u> in the amount of \$ <u>200.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0326</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Amount to be refunded:</td> <td style="width: 40%;">\$</td> </tr> <tr> <td>charged:</td> <td>\$</td> </tr> </table>	Amount to be refunded:	\$	charged:	\$																				
Amount to be refunded:	\$																									
charged:	\$																									
<p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>SEND ALL CORRESPONDENCE TO</p> <p>KINETIC CONCEPTS, INC.</p> <p>Attn: Nadeem G. Bridi</p> <p>P.O. Box 659508</p> <p>San Antonio, Texas 78265-9508</p> <p>USA</p> </div> <div style="width: 45%; text-align: right;">  SIGNATURE Nadeem G. Bridi NAME 42,361 REGISTRATION NUMBER </div> </div>																										

VACUUM ASSISTED CLOSURE SYSTEM
WITH HEATING AND COOLING PROVISION

RELATED APPLICATION:

This application claims priority to United States provisional patent application Serial No. 60/127,596 entitled VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION filed April 2, 1999. By this reference, the full disclosure, including the drawings, of U.S. provisional patent application Serial No. 60/127,596 is incorporated herein.

TECHNICAL FIELD:

The present invention relates to the healing of wounds. More specifically, the present invention relates to the vacuum assisted closure of wounds wherein localized heating or cooling is used to accelerate or retard the metabolic function of the inflammatory system in order to facilitate wound healing.

BACKGROUND ART:

Wound closure involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until recently, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can eventually cause wound dehiscence and additional tissue loss.

WO 00/59418

PCT/US00/08759

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative pressure, commonly referred to as vacuum assisted closure (VAC) therapy, typically involves mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, VAC therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While VAC therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the inflammatory process is very unique to the individual patient, even the addition of VAC therapy does not result in a fast enough response for closure of some wounds, especially when applied during the occlusion and initial cleanup and rebuilding stages. It is therefore a principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through controlled acceleration of the inflammatory response.

Additionally, and again at least partially attributable to the variance between patients, it is possible that a properly initiated inflammatory response may be taken too far, resulting in edema and pain. It is therefore another principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through controlled retardation of the inflammatory response.

DISCLOSURE OF THE INVENTION:

In accordance with the foregoing objects, the present invention – a method and apparatus for the controlled acceleration and/or retardation of the body's inflammatory response – generally comprises a foam pad for insertion substantially into a wound site, a

WO 00/59418

PCT/US00/08759

heating and cooling pad for application over the wound site and a wound drape for sealing enclosure of the foam pad and the heating and cooling pad at the wound site. According to the invention, the foam pad is placed in fluid communication with a vacuum source for promotion of fluid drainage while warm or cool fluid is circulated through the heating and cooling pad for the controlled acceleration or retardation, respectively, of the metabolic function portion of the body's inflammatory response.

According to the preferred embodiment of the present invention, a heating and cooling provision is added to the previously known VAC therapy to control the local metabolic function as part of the inflammatory response. By providing localized heating in combination with the otherwise ordinary VAC therapy, the overall inflammatory response can be synergistically accelerated to produce rapid capillary occlusion and earlier initiation of the cleanup and rebuilding stages. Likewise, in the event that the attending clinician determines that the inflammatory response has been over-activated, localized cooling may be provided in combination with the VAC therapy to retard the body's inflammatory response without sacrifice of the edema control and other aspects of the otherwise provided VAC therapy.

In the preferred embodiment of the present invention, the heating and cooling pad comprises a flexible and breathable water layer, generally comprising two sheets of RF-weldable material. The two sheets of the pad are RF-welded together in a waffle-like pattern, wherein a plurality of apertures is formed between a plurality of channels. The apertures allow the transpiration of moisture from the patient's skin while the channels allow the circulation, via a supply tube and a drainage tube, of warm or cool water, as required, through the pad for the heating or cooling thereof.

While the heating and cooling pad may be placed inside or outside of the wound drape during the heating aspect of the present invention, it is critical that the heating and cooling pad be placed inside of the wound drape during the cooling aspect of the present invention. In this manner, condensate formation on the interior of the drape, which may cause the drape's adhesive to loosen and ultimately result in loss of vacuum at the wound site, can be minimized. In particular, placing the heating and cooling pad inside the wound drape limits the surrounding moisture content to that existing and generated within the confines of the wound site, which is minimized by the suction aspect of the VAC therapy.

Because the cooling aspect of the present invention should be implemented in this manner and the clinician may indicate the need for cooling at any time after initiation of VAC therapy, the preferred method of the present invention comprises placing the heating and cooling pad beneath the wound drape, adjacent the foam pad and wound site, regardless

WO 00/59418

PCT/US00/08759

of whether heating or cooling is initially indicated. Upon placement of the pad, the wound drape is firmly adhered about the supply tube and drainage tube to prevent vacuum leakage.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions, the following drawings and exemplary detailed description and the claims appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS:

Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiment follows together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

Figure 1 shows, in partially cut away perspective view, the preferred embodiment of the present invention as applied to a mammalian wound site; and

Figure 2 shows, in top cross-sectional plan view, the heating and cooling pad of the invention of Figure 1.

BEST MODE FOR CARRYING OUT THE INVENTION:

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention – a vacuum assisted closure system with heating and cooling provision, the scope of which is limited only by the claims appended hereto.

Referring now to the figures, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into a wound site 12, a heating and cooling pad 13 for application over the wound site 12 and a wound drape 14 for sealing enclosure of the foam pad 11 and the heating and cooling pad 13 at the wound site 12. According to the invention, the foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage while warm or cool fluid is circulated through the heating and cooling pad 13 for the controlled acceleration or retardation, respectively, of the metabolic function portion of the body's inflammatory response.

According to the preferred embodiment of the present invention, the foam pad 11, wound drape 14 and vacuum source are implemented as known in the prior art, each of which is detailed in U.S. patent application Serial No. 08/517,901 filed August 22, 1995. By this reference, the full disclosure of U.S. patent application Serial No. 08/517,901 ("the '901 application"), including the claims and the drawings, is incorporated herein as though now

WO 00/59418

PCT/US00/08759

set forth in its entirety. Additionally, such a VAC system is readily commercially available through Kinetic Concepts, Inc. of San Antonio, Texas, U.S.A. and/or its subsidiary companies.

As detailed in the '901 application, the foam pad 11 preferably comprises a highly
5 reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction. As also detailed in the '901 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 15, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump.
10 Finally, the '901 application also details the wound drape 14, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '901 application are generally employed as known in the art with the
15 exception that the heating and cooling provision of the present invention is added to control the local metabolic function as part of the inflammatory response. By providing localized heating in combination with the otherwise ordinary VAC therapy, the overall inflammatory response can be synergistically accelerated to produce rapid capillary occlusion and earlier initiation of the cleanup and rebuilding stages. Likewise, in the event that the attending
20 clinician determines that the inflammatory response has been over-activated, localized cooling may be provided in combination with the VAC therapy to retard the body's inflammatory response without sacrifice of the edema control and other aspects of the otherwise provided VAC therapy.

In the preferred embodiment of the present invention, the heating and cooling pad 13
25 comprises a flexible and breathable water layer 16, generally comprising two sheets 17, 18 of RF-weldable material. The two sheets 17, 18 of the pad are RF-welded together in a waffle-like pattern, wherein a plurality of apertures 19 is formed between a plurality of channels 20. The apertures 19 allow the transpiration of moisture from the patient's skin 21 while the channels 20 allow the circulation, via a supply tube 22 and a drainage tube 23, of warm or
30 cool water, as required, through the pad 13 for the heating or cooling thereof.

While the heating and cooling pad 13 may be placed inside or outside of the wound drape 14 during the heating aspect of the present invention, it is critical that the heating and cooling pad 13 be placed inside of the wound drape 14 during the cooling aspect of the present invention. In this manner, condensate formation on the interior and near the edges of
35 the drape 14, which may cause the drape's adhesive to loosen and ultimately result in loss of

WO 00/59418

PCT/US00/08759

vacuum at the wound site 12, can be minimized. In particular, placing the heating and cooling pad 13 inside the wound drape 14 limits the surrounding moisture content to that moisture level existing and generated within the confines of the wound site 12, which is minimized by the suction aspect of the VAC therapy.

5 Because the cooling aspect of the present invention should be implemented in this manner and the clinician may indicate the need for cooling at any time after initiation of VAC therapy, the preferred method of the present invention comprises placing the heating and cooling pad 13 beneath the wound drape 14, adjacent the foam pad 11 and wound site 12, regardless of whether heating or cooling is initially indicated. Upon placement of the pad 13,
10 the wound drape 14 is firmly adhered about the supply tube 22 and the drainage tube 23 to prevent vacuum leakage.

 While the foregoing description is exemplary of the preferred embodiment of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible,
15 especially in light of this description, the accompanying drawings and the claims drawn hereto. For example, those of ordinary skill in the art will recognize that the heating and cooling pad 13 may be constructed in a wide variety of shapes, sizes and internal structures. Such an alternative embodiment may comprise the integration of the heating and cooling pad 13 into a multi-layered version of the wound drape 14. In any case, because the scope of the
20 present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the present invention, which is limited only by the claims appended hereto.

INDUSTRIAL APPLICABILITY:

25 The present invention is applicable to the wound healing arts.

WO 00/59418

PCT/US00/08759

CLAIMS:

What is claimed is:

1. A method for the promoting wound healing in mammals, said method comprising the
5 steps of:
applying a vacuum to a region of a wound site on a mammal; and
effecting a change in the mammal's inflammatory response at said region while said
vacuum is applied thereto.
- 10 2. The method for promoting wound healing as recited in claim 1, wherein said
effecting a change step comprises controlling the mammal's local metabolic function at said
region.
3. The method for promoting wound healing as recited in claim 2, wherein said
15 effecting a change step comprises accelerating the mammal's local metabolic function at said
region to encourage rapid capillary occlusion and accelerated initiation of the cleanup and
rebuilding steps of the mammal's inflammatory response.
4. The method for promoting wound healing as recited in claim 3, wherein said
20 effecting a change step comprises heating said region.
5. The method for promoting wound healing as recited in claim 2, wherein said
effecting a change step comprises retarding the mammal's local metabolic function as said
region to prevent over-activation of the mammal's inflammatory response.
- 25 6. The method for promoting wound healing as recited in claim 5, wherein said
effecting a change step comprises cooling said region.
7. The method for promoting wound healing as recited in any of the preceding claims,
30 wherein said applying a vacuum step comprises the steps of:
packing said wound site with a foam pad, said foam pad being in fluid
communication with a vacuum source;
sealing said region, including said foam pad, with a wound drape; and
communicating said vacuum from said vacuum source through said foam pad to said
35 region.

WO 00/59418

PCT/US00/08759

8. The method for promoting wound healing as recited in claim 7, wherein said effecting a change step comprises the steps of:

circulating a fluid about said region; and
controlling the temperature of said fluid to obtain said change.

5

9. The method for promoting wound healing as recited in claim 8, wherein said fluid is circulated about said region in a flexible envelope, said flexible envelope having an inlet and an outlet for fluid communication therethrough of said fluid.

10. The method for promoting wound healing as recited in claim 9, said method further comprising the step of sealing said flexible envelope, with said wound drape, between said foam pad and said wound drape.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

09877888-108201



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61F 7/00	A1	(11) International Publication Number: WO 00/59418
		(43) International Publication Date: 12 October 2000 (12.10.00)

(21) International Application Number: PCT/US00/08759

(22) International Filing Date: 31 March 2000 (31.03.00)

(30) Priority Data:
60/127,596 2 April 1999 (02.04.99) US

(71) Applicant (for all designated States except US): KINETIC CONCEPTS, INC. [US/US]; 8023 Vantage Drive, San Antonio, TX 78230 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HANNIGAN, Raymond, R. [US/US]; 3 Sanctuary Drive, San Antonio, TX 78248 (US); LEININGER, James, R. [US/US]; 304 Tower Drive, San Antonio, TX 78232 (US); BILTZ, Charles, I., Jr. [US/US]; 333 Wild Rose, San Antonio, TX 78209 (US); DILAZZARO, Frank [US/US]; 1107 Morgans Peak, San Antonio, TX 78258 (US); FASHEK, Christopher [US/US]; 4 Abby Wood, San Antonio, TX 78257 (US); JOHNSON, Royce, W. [US/US]; 114 Rimdale, Universal City, TX 78148 (US); SCHROEDER, Wayne, J. [US/US]; 13307 Bonn Heights, San Antonio, TX 78230 (US).

(74) Agents: COLTON, Wayne, J.; Wayne J. Colton, Inc., Suite 1108, The Milam Building, 115 East Travis Street, San Antonio, TX 78205 (US) et al.

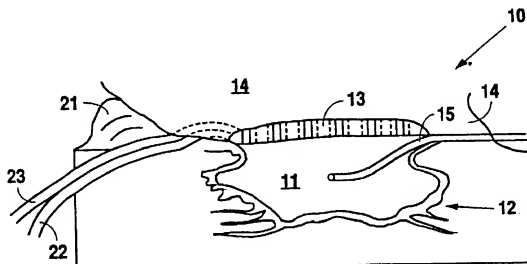
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SI, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION



(57) Abstract

A method, and apparatus (10) for the controlled acceleration, and/or retardation of the body's inflammatory response generally comprises a foam pad (11) for insertion substantially into a wound site, a heating, a cooling pad (13) for application over the wound site (12), a wound drape (14) or sealing enclosure of the foam pad (11), the heating, and cooling pad (13) at wound site (12). The foam pad (11) is placed in fluid communication with a vacuum source for promotion of the controlled acceleration or retardation of the body's inflammatory response. The heating, and cooling provision controls the local metabolic function as part of the inflammatory response.

1/1

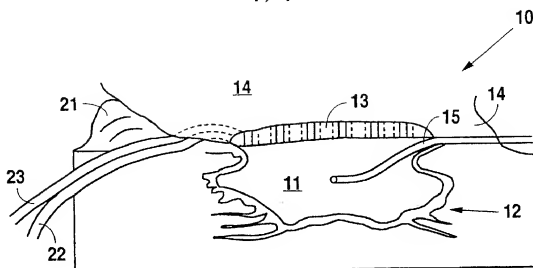


Fig. 1

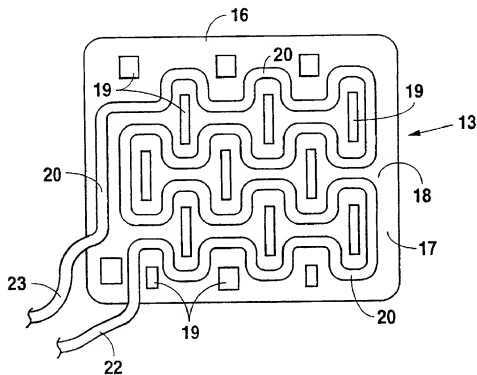


Fig. 2

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☒ Declaration Submitted with Initial Filing
OR
☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number VAC.482
First Named Inventor HANNIGAN, Raymond
COMPLETE IF KNOWN
Application Number /
Filing Date
Group Art Unit
Examiner Name

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY)

31 March 2000

as United States Application Number or PCT International

Application Number PCT/US00/08759 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
	US		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto

[Page 1 of 2]

Please type a plus sign (+) inside this box → ☐

PTO/SB/02A (11-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION**ADDITIONAL INVENTOR(S)****Supplemental Sheet**Page 1 of 2

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Charles I.		Blitz, Jr.	
Inventor's Signature		Date	
San Antonio	TX	US	US
Residence: City	State	Country	Citizenship
Mailing Address 333 Wild Rose			
Mailing Address			
City San Antonio	State TX	ZIP 78209	Country US
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Frank		Dilazzaro	
Inventor's Signature		Date	
San Antonio	TX	US	US
Residence: City	State	Country	Citizenship
Mailing Address 1107 Morgans Peak			
Mailing Address			
City San Antonio	State TX	ZIP 78257	Country US
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Christopher		Fashek	
Inventor's Signature		Date	
San Antonio	TX	US	US
Residence: City	State	Country	Citizenship
Mailing Address 4 Abby Wood			
Mailing Address			
City San Antonio	State TX	ZIP 78257	Country US

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

1003 100 24 00000900

09937937.100201

Please type a plus sign (+) inside this box ☐

PTO/SB/02A (11-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 2 of 2

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Wayne J.		Schroeder	
Inventor's Signature		Date	
San Antonio	TX	US	US
Residence: City	State	Country	Citizenship
Mailing Address 13307 Bonn Heights			
Mailing Address			
City San Antonio	State TX	ZIP 78230	Country US
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Royce W.		Johnson	
Inventor's Signature		Date 25 SEP 01	
Universal City	TX	US	US
Residence: City	State	Country	Citizenship
Mailing Address 114 Rimdale			
Mailing Address			
City Universal City	State TX	ZIP 78148	Country US
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
	State	Country	Citizenship
Mailing Address			
Mailing Address			
City	State	ZIP	Country

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION Utility or Design Patent Application

Direct all correspondence to: <input checked="" type="checkbox"/> Customer Number or Bar Code Label		30159		OR <input type="checkbox"/> Correspondence address below	
Name <u>Kinetic Concepts, Inc., Attn: Nadeem Bridi</u>					
Address <u>P.O. Box 659508</u>					
City <u>San Antonio</u>		State <u>TX</u>		ZIP <u>78265-9508</u>	
Country <u>US</u>		Telephone <u>210-255-4543</u>		Fax <u>210-255-4440</u>	
<p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>					
NAME OF SOLE OR FIRST INVENTOR: <input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle (if any)) <u>Raymond R.</u>			Family Name or Surname <u>Hannigan</u>		
Inventor's Signature <u>[Signature]</u>			Date <u>9-25-01</u>		
Residence: City <u>San Antonio</u>		State <u>TX</u>		Country <u>US</u>	
Citizenship <u>US</u>					
Mailing Address <u>3 Sanctuary Drive</u>					
City <u>San Antonio</u>		State <u>TX</u>		ZIP <u>78248</u>	
Country <u>US</u>					
NAME OF SECOND INVENTOR: <input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle (if any)) <u>James R.</u>			Family Name or Surname <u>Leininger</u>		
Inventor's Signature <u>[Signature]</u>			Date <u>9/25/01</u>		
Residence: City <u>San Antonio</u>		State <u>TX</u>		Country <u>US</u>	
Citizenship <u>US</u>					
Mailing Address <u>304 Tower Drive</u>					
City <u>San Antonio</u>		State <u>TX</u>		ZIP <u>78232</u>	
Country <u>US</u>					
<input checked="" type="checkbox"/> Additional inventors are being named on the <u>2</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.					